REMARKS

Applicants note with appreciation that the rejections of Claims 16-21 under 35 U.S.C. § 112, second paragraph and under 35 U.S.C. § 101 have been withdrawn.

Claims 16, 17, 21, 28-38, 46-49 and 65-68 have been amended. Claims 18-20 have been canceled. Claims 1-15 and 22-38 are withdrawn from consideration as being drawn to non-elected subject matter. Upon entry of these amendments, Claims 16-17, 21 and 39-68 will be pending and under consideration in the instant application.

Applicants acknowledge that process claims of Groups II and III (Claims 1-15 and 22-38) can be rejoined pursuant to M.P.E.P. § 821.04 once product claims of Group I are allowed. Applicants reserve the right to rejoin Claims 1-15 and 22-38 currently withdrawn from consideration.

I. AMENDMENTS TO THE CLAIMS

Claim 16 has been amended to include the phrase "sterile pharmaceutical composition suitable for intravenous administration into a human". Support for this amendment can be found, for example, on page 2, line 12, on page 14, lines 23-24 and on page 16, lines 17-19. Claim 17 has been amended to specify the content of the protein-lipid complex. Support for this amendment can be found, for example, on page 10, lines 19-20, on page 18, line 32 and on page 19, line 10 and lines 15-16 of the specification.

Claims 18-20 have been canceled in view of the amendments to Claim 17.

Claim 21 has been amended to depend from Claim 16.

Claims 28-38 have been amended to depend from Claim 27.

Claims 46-49 and 65-68 have been amended for grammatical correctness.

Therefore, no new matter has been introduced by these amendments. Accordingly, entry of the above-mentioned amendments is kindly requested.

II. THE REJECTION UNDER 35 U.S.C. §102(b)

Claims 17 and 54-68 are rejected under 35 U.S.C. 102(b) as being allegedly anticipated by Shackelford and Lebherz (Shackelford, J. and Lebherz, H. "Synthesis and Secretion of Apolipoprotein A_I by Chick Breast Muscle", *The Journal of Biological Chemistry* 258(11):7175-7180 (1983)). This rejection is traversed. Reconsideration is kindly requested.

It is well established law that every limitation of a claim must appear in a single prior art reference for it to anticipate the claim. *Gechter v. Davidson* 116 F.3d 1454, 43 USPQ2d 1030 (Fed. Cir. 1997). Applicants respectfully submit that Shackelford and Lebherz do not teach each and every limitation of Claim 17, and as such the reference fails to anticipate Claim 17.

Claim 17 has been amended to recite: "A protein-lipid complex consisting of a purified non-human animal ApoA-I protein and a lipid, wherein the lipid is sphingomyelin or dipalmitoylphosphatidylcholine, and wherein said complex ... is suitable for administration to a human." The reference cited by the Examiner discloses a chicken breast muscle-derived apolipoprotein component of lipoprotein particles secreted from muscle explants (see, *e.g.*, p.7178). The cited art does not disclose a protein-lipid complex wherein the lipid is sphingomyelin or dipalmitoylphosphatidylcholine nor does the reference disclose such a complex being suitable for administration to a human, as recited in Claim 17. In particular, the cited reference does not disclose a sterile pharmaceutical composition as claimed. In sum, each and every limitation of Claim 17, or of Claims 54-68 that depend from Claim 17, is not found in the cited reference.

Accordingly, Claims 17 and 54-68 are not anticipated by Shackelford and Lebherz. Therefore, it is respectfully requested that the rejection under 35 U.S.C. 102(b) be withdrawn.

III. THE REJECTION UNDER 35 U.S.C. §103

Claims 16, 18-20 and 39-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shackelford and Lebherz in view of Dasseux *et al.* (U.S. Patent 6,037,323). The rejection is moot with respect to Claims 18-20 in view of cancellation of these claims. Applicants respectfully traverse the rejection of Claims 16 and 39-53.

The legal standard of *prima facie* obviousness requires that three criteria be met. First, the prior art, alone or in combination, must teach or suggest each and every limitation of the claimed invention. *In re Royka*, 490 F.2d 981, 180 USPQ 580, 582 (CCPA 1974). Second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the reference teachings in the manner suggested by the Patent Office. *In re Grabiak*, 226 USPQ 870, 872 (Fed. Cir. 1985). Third, the skilled artisan, in light of the teachings of the prior art, must have had a reasonable expectation that the modification or combination suggested by the Patent Office would be successful. *In re Dow*, 5 USPQ2d 1529,

1531-1532 (Fed. Cir. 1988). If any one of these criteria is not met, *prima facie* obviousness is not established. Applicants respectfully submit that the art cited by the Examiner does not teach or suggest each and every limitation in the instant claims, nor is there a suggestion or motivation to combine the teachings of Shackelford and Dasseux to arrive at Claims 16 and 39-53.

As amended, Claim 16 recites "a sterile pharmaceutical composition suitable for intravenous administration into a human comprising the protein-lipid complex as recited in Claim 17 and a pharmaceutically acceptable carrier, excipient or diluent." Shackelford and Lebherz disclose an ApoA-I-like protein that is described as likely to be associated in lipoprotein particles secreted from explants derived from chicken muscle. What Shackelford and Lebherz do not teach or suggest is a protein-lipid complex consisting of a purified non-human animal ApoA-I protein and a lipid, wherein the lipid is sphingomyelin or dipalmitoylphosphatidylcholine.

Moreover, Shackelford and Lebherz do not teach or suggest a sterile pharmaceutical composition suitable for intravenous administration into a human. Instead, Shackelford and Labherz merely describe the identification of an ApoA-I-like protein secreted from chicken breast muscle.

Dasseux *et al.* does not remedy the deficiencies of Shackelford and Lebherz. For example, Dasseux *et al.* does not teach or suggest a protein-lipid complex consisting of a purified *non-human animal* ApoA-I protein and a lipid, wherein the lipid is sphingomyelin or dipalmitoylphosphatidylcholine. Indeed, the reference emphasizes the advantages of small specific synthetic proteins, and thus teaches away from the use of non-human much less natural ApoA-I proteins in the protein-lipid complex recited in the amended claims. Nor does Dasseux *et al.* teach or suggest a pharmaceutical composition comprising a non-human animal ApoA-I protein-containing protein-lipid complex suitable for administration to a human.

The Patent Office contends that the suggestion or motivation to combine the references is because of the benefits discussed by Dasseux *et al.* when recombinant ApoA-I protein is administered *in vivo* to animals (*e.g.*, pages 4-5 of Office Action mailed May 28, 2004). It is respectfully submitted, however, that these benefits were not in humans using the composition recited in Claim 16, nor is there any suggestion or motivation to combine the references provided in the cited art to arrive at the instant claims whether in order to achieve any such benefits or for any other reason. Again, Dasseux *et al.* teaches away from use of

natural ApoA-I protein regardless of whether human or non-human composition is being used. As a result, the claimed invention cannot be obvious over the cited art.

Based on a aforementioned discussion, Applicants respectfully submit that neither Claim 16 nor Claims 39-53 that depend from Claim 16 are obvious over the cited art. Therefore, it is respectfully requested that the rejection of Claims 16 and 39-53 under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

Applicants submit that Claims 16-17, 21 and 39-68 satisfy all the criteria for patentability and are in condition for allowance. An early indication of the same is therefore kindly solicited.

No fee other than the RCE fee is believed to be due at this time. However, if the Office determines that other fees are, in fact, due, pursuant to 37 C.F.R. §1.136 (a)(3), the Commissioner is authorized to charge all required fees, fees under 37 C.F.R. §1.17 and all required extension of time fees, or credit any overpayment, to Jones Day U.S. Deposit Account No. 503013 (Attorney Docket No. 10173-084-999).

Respectfully submitted,

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